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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/092,751 | 03/07/2002 | Paul Hebeisen | 20858 | 1027 |

151 7590 03/22/2004
HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
340 KINGSLAND STREET
NUTLEY, NJ 07110

EXAMINER

BERNHARDT, EMILY B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1624

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/092,751 | Applicant(s) HEBEISEN ET AL. | |
| | Examiner Emily Bernhardt | Art Unit 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 33 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-19 is/are allowed.
- 6) ☒ Claim(s) 1-8, 20-32 and 34 is/are rejected.
- 7) ☒ Claim(s) 9-12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

In view of applicants' response filed 12/29/03 the following still applies.

Applicant's election without traverse of I in Paper filed 12/29/03 is acknowledged.

Receipt of new abstract is acknowledged. However the new abstract is objected to because there is a minor typo in the heading which can be rectified by either applicants in a subsequent response or by the examiner if the case is ever allowed. Note the missing "e" in "Invention". Also the intended use recited on the last line should include obesity . Correction is required. See MPEP § 608.01(b).

Claims 1-7 and 34 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reason given previously as reason #2. Contrary to what applicants assert reasoning has been provided in making this rejection, namely the lack of representative working examples vs. the scope of the claims and the state of the prior art which are factors considered in the Wands decision discussed in the previous action. Thus given the breadth of the claims, the level of unpredictability in the art and the lack of direction (i.e. test data) provided as to what rings, ring systems as "heterocyclyl" in the claims might work, this rejection is maintained. Note in Surrey previously cited, in which testing done on a group of homogeneous compounds was deemed not sufficient to support claims to various hetero groups of a narrower range than is being claimed herein

and located at only one position in the formula. Enablement of individual species does not necessarily provide enablement of the genus as a whole. Note In re Langer 183 USPQ 288. Describing the invention as broadly as it is claimed does not necessarily enable one how to make and use the invention. Applicants provide no sound reasoning why one skilled in the art would expect such diverse substituted derivatives as embraced herein to behave similarly to compounds made and tested, which are more similar to each other than to remaining scope. Literal support for the claims was also present in Surrey previously cited. If Surrey solely required literal support then the earlier Cauvallito decision (127 USPQ 202) would not have been heavily relied on as it was. Note the following quote taken from Cauvallito (regarding literal support at p.205, left column: "The mere statement of an inventive concept, however, is not a sufficient basis for claiming it. Sufficient information must be given to enable those skilled in the art to practice the invention." . The limited data provides no clear evaluation of which heterocyclic groups at various positions out of the many claimed might affect potency to a large or small degree. Applicants has failed to establish that the compounds tested are structurally and functionally similar to those tested herein or to known compounds having the same activities.

The 102 rejections of the previous action are overcome by applicants' amendment to the scope at R6. The 103 rejection is withdrawn as Adams does not teach alkyl at instant R6 but rather specifically at the 3-position for hexahydro analogs.

The following rejections apply. Bentley (WO'169) of record was published not after (as originally perceived) but before applicants' US filing date and a review of the claims show that not all are entitled to 119 benefit and thus Bentley is a competent reference as set forth below.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before

November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-8 and 32 are rejected under 35 U.S.C. 102(a) as being anticipated by Bentley (WO'169). The commonly assigned publication describes many instant tetrahydro derivatives having alkyl,hydroxyalkyl at the 4-position for use as intermediates to making hexahydro analogs. See formulas D,D1 and D2 in the reaction sequences and ultimate species on p.36 with S or R configuration, p.51 compound (d),p.76-77 and 80 compound (c) in all instances, pp.82-83 compound (a), and p.90,95,100-107 and 111 for additional tetrahydro derivatives. Claims rejected herein are not entirely described and/or enabled in foreign priority papers. Compare scope at R6 which is narrower in said papers and further fusion at R3/R4 is not described compared to main claim 1 and claim 8. While claims 2-7 are described said claims do not comply with 35 USC 112 par.one for reasons maintained in the above 112 rejection for claims 1-7. Claim 32 recites a variety of species which are not all described in priority papers. See 1st, 4th-9th species which are not seen in priority document. Note for 119 benefit there must be clear compliance with 35 USC 112,description and enablement as was decided in In re Gostelli 10 USPQ 2nd 1614; Kawai v. Metlesics 178 USPQ 158.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 20-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bentley. Species embraced in these claims are also not described in priority document. While not anticipated by Bentley they are obvious variants for making corresponding hexahydro derivatives since the functional groups present in these species are all taught as preferred embodiments beginning on p.10-11. Compound in claims 20-21 is a position isomer of one described on p.51. The same can be said for compound in claims 24-25 vs compound (d) on p.106 and for claims 30-31 vs compound (b) on p.104. Compound in claims 22-23 differ only in being the 6-ethyl analog of 6-Me species on p.106. Compound in claims 26-27 only differs in nature of halo at 6-position compared to 6-Cl and 6-Br analogs in Bentley. See p.95 and p.111. Species in claims 29-30 only differs in nature of substituent at 6-position- cyano vs halo,alkyl in Bentley. However, Bentley teaches the interchangeability of all aforementioned groups and at all ring positions of the benzene ring for making corresponding final products. Thus it would have been obvious to one skilled in the art at the time the instant invention was made to modify species in Bentley pointed out above by changing nature or position of

halo,alkyl group with those groups particularly claimed herein and in so doing obtain additional compounds for use as synthetic precursors in view of the equivalency teachings outlined above.

Claims 1-8 and 32 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 10/396242 which has a common inventors with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if published under 35 U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application. The copending application has an effective filing date of 7/25/01 corresponding to abandoned parent. It is the US equivalent of WO'169 applied above and thus the same species as described above are disclosed but not claimed therein. The copending case is a competent reference,if allowed, for the same reason discussed above regarding denial of 119 benefit.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR

1.131. This rejection may not be overcome by the filing of a terminal disclaimer.

See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

Claims 20-31 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 10/396242 which has a common inventors with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application. As stated above the disclosure of the copending case corresponds to Bentley (WO'169) and thus the species in these claims are rejected as above in Bentley.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made,

owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(1)(1) and § 706.02(1)(2).

A review of the current claims in 10/396242 show no overlap with instant claimed subject matter and the tetrahydro species particularly claimed in the copending case are distinct being further substituted at the 2-position.

Claims 9-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 13-19 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Bernhardt whose telephone number is (571) 272-0664.

If attempts to reach the examiner by phone are unsuccessful, the supervisor for AU 1624, Dr. Mukund Shah, can be reached at (571)272-0674.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.



EMILY BERNHARDT

PRIMARY EXAMINER

Group 1600